JUL 28 2011

510(k) Summary

K110571

Submitter:	Jonathan Javitt, M.D., M.P.H., Chief Executive Officer Telcare, Inc. 2 Bethesda Metro Center, Suite 1350 Bethesda, MD, 20814
Contact Person:	Jonathan Javitt, M.D., M.P.H., Chief Executive Officer Telcare, Inc. 2 Bethesda Metro Center, Suite 1350 Bethesda, MD, 20814 Telephone: (240) 396-6003, Fax: 877-777-4710 Email: JJavitt@telcare.com
Date Prepared:	July 27, 2011
Trade Names:	Telcare Blood Glucose Monitoring System, Telserve Data Management System, Telcare Blood Glucose Test Strips, Telcare Glucose Control Solutions
Classification Names:	Glucose test system, 21 CFR 862.1345, Class II Quality control material (assayed and unassayed), 21 CFR 862.1600, Class I Calculator/data processing module for clinical use, 21 CFR 862.2100, Class I Exempt (non exempt is associated with blood glucose monitoring system)
Product Codes:	NBW, CGA, JJX, JQP
Predicate Devices:	AutoSure Voice II Blood Glucose Monitoring System (BGM) - k102037, MCT-Diabetes (Data Management Software) – k073699, Gluco Track Blood Glucose Monitoring System (control solutions) – k062799
Device Description:	The Telcare Blood Glucose Monitoring System consists of the Telcare Blood Glucose Meter (BGM), Telcare Blood Glucose Test Strips, and Telcare Glucose Control Solutions. The Telcare BGM, when used with the Telcare Test Strips, quantitatively measures glucose in capillary whole blood. The Telcare Control Solutions verify the performance of the Telcare Test Strips. An embedded cellular module within the Telcare BGM enables wireless communication between the meter and Telcare's remote database, called the Telserve Data Management System (Telserve). The Telserve Data Management System serves as an accessory to blood glucose meters to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. The software system consists of two different levels of functionality: 1) Telserve Data Management System – Home Use and 2) Telserve Data Management System – Professional Use

510(k) Summary (Cont'd)

Intended Use:	**Telcare Blood Glucose Monitoring System** The Telcare Blood Glucose Monitoring system is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is intended for lay use by persons with diabetes to aid in diabetes management. It is indicated for use at home (over the counter [OTC]) and should be used only by a single patient and should not be shared. Testing is done outside the body (*in vitro* diagnostic use). The Telcare Blood Glucose Monitoring System consists of the Telcare Blood Glucose Meter, Telcare Blood Glucose Test Strips, and Telcare Glucose Control Solutions. The Telcare Blood Glucose Monitoring system is not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. The Telcare Blood Glucose Meter uses cellular data transmission to send test results to Telcare's remote database, Telserve, and to receive messages from Telserve. The Telcare Blood Glucose Monitoring System is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment. **Telcare Blood Glucose Test Strips** The Telcare Blood Glucose Test Strips are to be used with the Telcare Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, palm, or forearm. These test strips are intended for lay use by persons with diabetes and should only be used by a single patient. They are not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. **Telcare Glucose Control Solutions** The purpose of the control solution test is to validate the performance of the Telcare Blood Glucose Monitoring System by using a test solution with a known amount of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

510(k) Summary (Cont'd)

Intended Use (Cont'd)	The **Telserve Data Management System – Home Use (Telserve – Home)** is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telserve collects data from blood glucose meters such as the Telcare BGM. Telserve – Home is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment. The **Telserve Data Management System – Professional Use (Telserve – Pro)** is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telserve collects data from blood glucose meters such as the Telcare BGM.
Technological Characteristics	The Telcare Blood Glucose Monitoring System consists of a glucose meter that can wirelessly transmit data to a remote database using standard cellular technology embedded within the glucose meter. The meter uses biosensor test strips. Telserve Data Management System consists entirely of software run on a central server.
Non-Clinical Testing	Telcare BGM: Minimum Sample Volume, Linearity, Detection Limit, Precision, Hematocrit, Altitude, Humidity/Temperature, and Interfering Substances testing were done. Control Solution Qualification was conducted. EMC, Electrical Safety and FCC testing were conducted. Software verification and validation were done. All testing demonstrated safety and effectiveness of the Telcare Blood Glucose Monitoring system and substantial equivalence to the predicate. Telserve Data Management System: Software verification and validation demonstrated safety and effectiveness of the Telserve remote database and substantial equivalence to the predicate.

510(k) Summary (Cont'd)

Clinical Testing:	Telcare Blood Glucose Monitoring (BGM) System: A User Performance Study was conducted to evaluate the ease of use of the Telcare BGM and ease of understanding of the Telcare BGM user manual. An Accuracy and User Performance Study was conducted with professional and self-testing with fresh fingertip, palm and forearm testing. User control solution testing was conducted. A User Performance Study was conducted to evaluate the ease of use of the Telcare BGM Test Strip Insertion Process and ease of understanding of the Telcare BGM Test Strip Insertion instructions in the user manual. Telserve Data Management System (Telserve): A User Performance Study was conducted to evaluate the ease of use of Telserve-Home and ease of understanding of the Telserve – Home user manual. A User Performance Study was conducted to evaluate the ease of use obtaining login credentials to Telserve and ease of understanding of the Telserve – Home user manual. A User Performance Study was conducted to evaluate the ease of use of Telserve-Pro, the ease of use of obtaining login credentials, and ease of understanding of the Telserve – Pro user manual. The results show Telcare BGM System and Telserve showed substantial equivalence to the predicate devices.
Conclusion:	The Telcare Blood Glucose Monitoring System and its accessory Telserve Data Management System are substantially equivalent to their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUL 28 2011

Telcare, Incorporated
c/o Dr. Jonathan C. Javitt
Chief Executive Officer
3 Bethesda Metro Center Suite 430
Bethesda, MD 20814

Re: k110571
Trade Name: Telcare Blood Glucose Monitoring System, Telserve Data Management System – Home Use, Telserve Data Management System – Professional Use
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX, JQP
Dated: July 8, 2011
Received: July 11, 2011

Dear Dr. Javitt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110571

Device Name: Telcare Blood Glucose Monitoring System
Telserve Data Management System – Home Use
Telserve Data Management System – Professional Use

Indications for Use:

Telcare Blood Glucose Monitoring System
The Telcare Blood Glucose Monitoring system is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is intended for lay use by persons with diabetes to aid in diabetes management. It is indicated for use at home (over the counter [OTC]) and should be used only by a single patient and should not be shared. Testing is done outside the body (*in vitro* diagnostic use). The Telcare Blood Glucose Monitoring System consists of the Telcare Blood Glucose Meter, Telcare Blood Glucose Test Strips, and Telcare Glucose Control Solutions. The Telcare Blood Glucose Monitoring system is not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. The Telcare Blood Glucose Meter uses cellular data transmission to send test results to Telcare's remote database,Telserve, and to receive messages from Telserve. The Telcare Blood Glucose Monitoring System is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.

Telcare Blood Glucose Test Strips
The Telcare Blood Glucose Test Strips are to be used with the Telcare Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, palm, or forearm. These test strips are intended for lay use by persons with diabetes and should only be used by a single patient. They are not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __X___ (21 CFR Part 801 Subpart C)

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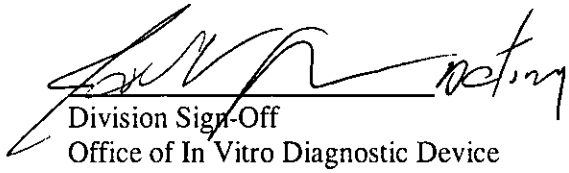
Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



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Office of In Vitro Diagnostic Device
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Telcare Glucose Control Solutions
The purpose of the control solution is to validate the performance of the Telcare Blood Glucose Monitoring System by using a test solution with a known amount of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

Telserve Data Management System - Home Use
The Telserve Data Management System - Home Use (Telserve - Home) is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telserve collects data from blood glucose meters such as the Telcare BGM. Telserve - Home is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.

Telserve Data Management System – Professional Use
The Telserve Data Management System – Professional Use (Telserve – Pro) is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telserve collects data from blood glucose meters such as the Telcare BGM.

Prescription Use ___X___ And/Or Over the Counter Use __X___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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